

CASSLING DIAGNOSTIC IMAGING

memorandum

DATE: February 16, 1998

TO: Dockets Management Branch
(HFA-305) Food and Drug Administration
12420 Parklawn Dr., Rm. 1-23
Rockville, MD 20857

FROM: Gary Nie, CDI ^{GN}

RE: Proposed Rule Change on Remarketing Equipment - [Docket No. 97N-0477]

0685 '98 APR -2 AIO:JA

Cassling Diagnostic Imaging has been refurbishing medical equipment for about four years and is registered with the FDA as a reconditioner/rebuilder. We have always followed the GMP's to insure the highest quality for our customers. We feel that the GMP's and the quality of the equipment being sold is a very important issue, and we show this belief through our ISO 9002 Certification which we obtained last year.

With this in mind, we feel that medical equipment refurbishment companies must meet a level of quality that will insure that the end-user is buying a product that will give them optimum performance for their patients. In regards to the four proposed questions, I have the following comments.

SECTION V Responses:

- Q1. (Definitions). The definitions you have spelled out look fine.
- Q2. (Evidence). I do not know of any documented problems, just comments from customers that had problems from dealing with poor refurbishers in the past.
- Q3. (Regulatory Concern). I feel that any person (company) that sells Medical Devices should track where it came from and who it was sold to, along with the proper paper work to meet FDA tracking. Also, there should be proof that the equipment meets proper working conditions to insure the customer that it will meet their state and FDA inspections.
- Q4. (Regulatory Requirements). I feel that refurbishers and servicers should meet your proposed minimum requirements and As Is remarketers should have to provide some paper work on where they bought the equipment and who they sold it to. Also, some type of paper work should be provided to show the equipment meets all standards when removed from customer site and that it will meet standards when they sell it.

I hope my comments will help. I am currently the Director of Refurb here at CDI and have had 23 years of experience at Picker, where I developed their refurb center using GMP's and FDA regulations. This experience could provide a valuable resource for your discussions and if at all possible I would like to be there when this important issue is reviewed.

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